

TRAITÉ DE COOPÉRATION EN MATIÈRE DE BREVETS

PCT

RAPPORT PRÉLIMINAIRE INTERNATIONAL SUR LA BREVETABILITÉ

(chapitre I du Traité de coopération en matière de brevets)

(règle 44bis du PCT)

| | | |
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| Référence du dossier du déposant ou du mandataire 347110/D21813 | POUR SUITE À DONNER Voir le point 4 ci-dessous | |
| Demande internationale no. PCT/FR2004/003287 | Date du dépôt international (<i>jour/mois/année</i>) 17 December 2004 (17.12.2004) | Date de priorité (<i>jour/mois/année</i>) 23 December 2003 (23.12.2003) |
| Classification internationale des brevets (8 ^e édition, sauf indication d'une #dition ant#rieure) Voir les informations pertinentes dans le formulaire PCT/ISA/237 | | |
| Déposant PIERRE FABRE MEDICAMENT | | |

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|--|---|-------------------|--------------------------------------|----------|---------------------------------------|--|--------------------------------------|--------------------------------|--|---|--------------------------------------|--------------------------|---------------------------------------|---|--|--|
| <p>1. Le présent rapport préliminaire international sur la brevetabilité (chapitre I) est établi par le Bureau international au nom de l'administration chargée de la recherche internationale selon la règle 44bis.1.a).</p> <p>2. Ce RAPPORT comprend un total de 5 feuilles, y compris la présente feuille de couverture.</p> <p>Dans les feuilles jointes, toute référence à l'opinion écrite de l'administration chargée de la recherche internationale doit être entendue, à la place, comme une référence au rapport préliminaire international sur la brevetabilité (chapitre I).</p> | | | | | | | | | | | | | | | | |
| <p>3. Le présent rapport contient des indications relatives aux points suivants :</p> <table border="0"> <tr> <td><input checked="" type="checkbox"/> Cadre n° I</td> <td>Base de l'opinion</td> </tr> <tr> <td><input type="checkbox"/> Cadre n° II</td> <td>Priorité</td> </tr> <tr> <td><input type="checkbox"/> Cadre n° III</td> <td>Absence de formulation d'opinion quant à la nouveauté, l'activité inventive et la possibilité d'application industrielle</td> </tr> <tr> <td><input type="checkbox"/> Cadre n° IV</td> <td>Absence d'unité de l'invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Cadre n° V</td> <td>Déclaration motivée selon l'article 35.2) quant à la nouveauté, l'activité inventive et la possibilité d'application industrielle; citations et explications à l'appui de cette déclaration</td> </tr> <tr> <td><input type="checkbox"/> Cadre n° VI</td> <td>Certains documents cités</td> </tr> <tr> <td><input type="checkbox"/> Cadre n° VII</td> <td>Certaines irrégularités relevées dans la demande internationale</td> </tr> <tr> <td><input type="checkbox"/> Cadre n° VIII</td> <td>Certaines observations relatives à la demande internationale</td> </tr> </table> <p>4. Le Bureau international communiquera le présent rapport aux offices désignés conformément aux règles 44bis.3.c) et 93bis.1 mais pas avant l'expiration du délai de 30 mois à compter de la date de priorité (règle 44bis.2), sauf si le déposant a présenté une requête expresse à cet égard en vertu de l'article 23.2).</p> | <input checked="" type="checkbox"/> Cadre n° I | Base de l'opinion | <input type="checkbox"/> Cadre n° II | Priorité | <input type="checkbox"/> Cadre n° III | Absence de formulation d'opinion quant à la nouveauté, l'activité inventive et la possibilité d'application industrielle | <input type="checkbox"/> Cadre n° IV | Absence d'unité de l'invention | <input checked="" type="checkbox"/> Cadre n° V | Déclaration motivée selon l'article 35.2) quant à la nouveauté, l'activité inventive et la possibilité d'application industrielle; citations et explications à l'appui de cette déclaration | <input type="checkbox"/> Cadre n° VI | Certains documents cités | <input type="checkbox"/> Cadre n° VII | Certaines irrégularités relevées dans la demande internationale | <input type="checkbox"/> Cadre n° VIII | Certaines observations relatives à la demande internationale |
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| <input type="checkbox"/> Cadre n° IV | Absence d'unité de l'invention | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Cadre n° V | Déclaration motivée selon l'article 35.2) quant à la nouveauté, l'activité inventive et la possibilité d'application industrielle; citations et explications à l'appui de cette déclaration | | | | | | | | | | | | | | | |
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| <input type="checkbox"/> Cadre n° VIII | Certaines observations relatives à la demande internationale | | | | | | | | | | | | | | | |

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| Bureau international de l'OMPI 34, chemin des Colombettes 1211 Geneva 20, Switzerland no de télécopieur +41 22 338 82 70 | Date d'établissement du présent rapport 29 August 2006 (29.08.2006) |
| | Fonctionnaire autorisé Athina Nickitas-Etienne e-mail: pt04@wipo.int |

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing **See Form PCT/ISA/210**
(day/month/year) **(sheet 2)**

Applicant's or agent's file reference

347110/D21813

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/FR2004/003287

International filing date (day/month/year)

17.12.2004

Priority date (day/month/year)

23.12.2003

International Patent Classification (IPC) or both national classification and IPC

A61K31/4375, A61P35/00, A61K9/08, A61K47/12

Applicant

PIERRE FABRE MEDICAMENT

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/FR2004/003287

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/FR2004/003287

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|------|-----|
| Novelty (N) | Claims | 1-13 | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 1-13 | NO |
| Industrial applicability (IA) | Claims | 1-13 | YES |
| | Claims | | NO |

2. Citations and explanations:

Reference is made to the following documents:

D1: US 4 923 876 A, which describes ready-to-use injectable preparations of vinca alkaloids at controlled pH (3.0-5.0);

D2: EP 0 298 192 A, which describes ready-to-use injectable preparations of vinca dimer salts at controlled pH (3.0-5.5);

D3: US 4 619 935 A, cited in the application, which describes ready-to-use injectable preparations of vincristine at controlled pH (3.0-5.0);

D4: Hill Bridget et al., Current Pharmaceutical Design, vol. 7, no. 13, pages 1199-1212, (2001), which illustrates the pharmacological profile of vinflunine and possible future uses thereof.

Unless otherwise indicated, reference is made to the passages cited in the international search report.

None of the documents cited mentions a ready-to-use vinflunine solution, and hence the subject matter of claims 1-13 appears to be novel (PCT Article 33(1) and (2)).

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/FR2004/003287

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

All the same, D1-D3 describe ready-to-use injectable solutions of vincristine, vinblastine, vindesine. All these vinca alkaloids have quite similar structures and problems of sterility due to the fact that heat sterilization is impossible.

The three documents can be considered to be the closest prior art. The difference between them and the present application is the specific alkaloid. The problem is that of obtaining a ready-to-use stable vinca alkaloid preparation. The solution proposed in the case of the other molecules is to control the pH (between 3 and 5.5) with a buffer, for example acetate.

A person skilled in the art would adopt the same solution for a preparation of vinflunine, given the very great structural similarities with vincristine, vinblastine and vindesine molecules. For this reason, the presence of an inventive step is not recognized for claims 1-13.